

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
cchevalier@gibbonslaw.com

Of Counsel:

David I. Berl
Elise Baumgarten
Kevin Hoagland-Hanson
Rebecca A. Carter
Falicia Elenberg (*pro hac vice* pending)
WILLIAMS & CONNOLLY LLP
725 12th St. NW
Washington, DC 20005
(202) 434-5000
dberl@wc.com
ebaumgarten@wc.com
khoagland-hanson@wc.com
rebeccacarter@wc.com
felenberg@wc.com

*Attorneys for Plaintiffs AstraZeneca Pharmaceuticals LP,
AstraZeneca UK Limited, Kudos Pharmaceuticals Limited,
The University of Sheffield, and
MSD International Business GmbH*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS)
LP, ASTRAZENECA UK LIMITED,)
KUDOS PHARMACEUTICALS LIMITED,)
THE UNIVERSITY OF SHEFFIELD, and)
MSD INTERNATIONAL BUSINESS)
GMBH,) C.A. No. 3:23-cv-00796 (RK)(TJB)
)
)
Plaintiffs,)
)
v.)
)
NATCO PHARMA LIMITED and NATCO)
PHARMA INC.,)
)
Defendants.)

**STIPULATION AND ORDER OF
DISMISSAL OF CERTAIN COUNTS**

WHEREAS, Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets; and

WHEREAS, Defendants Natco Pharma Limited and Natco Pharma, Inc. (collectively, “Defendants”) submitted Abbreviated New Drug Application (“ANDA”) No. 218044 (“Natco’s ANDA”) to obtain approval from the United States Food and Drug Administration (“FDA”) to make, use, offer for sale, or sell within the United States, or import into the United States generic versions of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg (hereinafter, “Natco’s ANDA Products”); and

WHEREAS, as relevant to this Stipulation, Natco’s ANDA contained so-called “Paragraph IV Certifications” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that U.S. Patent Nos. 7,449,464 (“the ’464 patent”), 8,475,842 (“the ’842 patent”) and 8,859,562 (“the ’562 patent”) are invalid or would not be infringed by Natco’s ANDA Products; and

WHEREAS, Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield and MSD International Business GmbH (collectively, “Plaintiffs”) filed an action against Defendants for infringement of the ’464 patent, the ’842 patent, and the ’562 patent under 35 U.S.C. § 271 (ECF No. 1); and

WHEREAS, after the Complaint was filed in this action, the United States Patent and Trademark Office issued U.S. Patent No. 11,633,396 (“the ’396 patent”); and

WHEREAS, on May 19, 2023, the ’396 patent was listed in the *Approved Drug Products with Therapeutic Equivalent Evaluations* (“Orange Book”) in connection with NDA No. 208558; and

WHEREAS, Defendants have filed counterclaims against Plaintiffs for the ’464 patent, the ’842 patent, the ’562 patent and the ’396 patent (ECF No. 36); and

WHEREAS, on October 17, 2023, Kudos Pharmaceuticals Limited, AstraZeneca UK Ltd., AstraZeneca Pharmaceuticals LP, and MSD International Business GmbH executed a Covenant Not to Sue with respect to the '842 patent and the '396 patent.

IT IS HEREBY STIPULATED AND AGREED BY AND BETWEEN THE RESPECTIVE PARTIES THAT:

1. The parties agree that, as a result of the foregoing, all claims, counterclaims, and affirmative defenses between Plaintiffs and Defendants with respect to the '842 patent and the '396 are hereby **DISMISSED WITHOUT PREJUDICE** pursuant to Federal Rule of Civil Procedure 41(a)(1), including
 - a. Counts III and IV of Plaintiffs' Complaint, ECF No. 1;
 - b. Defendants' counterclaim Counts III, IV, VII and VIII of Defendants' First Amended Answer, Affirmative Defenses and Counterclaims to Complaint for Patent Infringement, ECF No. 36;
 - c. Defendants' affirmative defenses of Defendants' First Amended Answer, Affirmative Defenses and Counterclaims to Complaint for Patent Infringement, ECF No. 36, with respect to the '842 patent and the '396 patent; and
 - d. Defendants' Prayer for Relief of Defendants' First Amended Answer, Affirmative Defenses and Counterclaims to Complaint for Patent Infringement (a), (b), ECF No. 36, with respect to the '842 patent and the '396 patent;
2. For clarity and the avoidance of doubt, this Stipulation and Order does not relate to, dismiss, or in any way affect any claims, counterclaims, or affirmative defenses pending between Plaintiffs and Defendants relating to the '464 patent or the '562 patent.
3. Each party shall bear its own costs, disbursements, and attorney fees.

Dated: November 8, 2023

s/Charles H. Chevalier
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone No.: (973) 596-4500
cchevalier@gibbonslaw.com

s/James S. Richter
James S. Richter
MIDLIDGE RICHTER LLC
645 Martinsville Road
Basking Ridge, New Jersey 07920
(908) 626-0622
jrichter@midlige-richter.com

Of Counsel:

David I. Berl
Elise Baumgarten
Kevin Hoagland-Hanson
Rebecca A. Carter
Felicia Elenberg
WILLIAMS & CONNOLLY LLP
725 12th St. NW
Washington, DC 20005
(202) 434-5000
dberl@wc.com
ebaumgarten@wc.com
khoagland-hanson@wc.com
rebeccacarter@wc.com
felenberg@wc.com

Of Counsel:

Kevin Warner
William A. Rakoczy
Paul J. Molino
Greg L. Goldblatt
RAKOCZY MOLINO MAZZOCHI SIWIK
LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60654
(312) 527-2157

*Attorneys for Defendants Natco Pharma Ltd.
and Natco Pharma, Inc.*

*Attorneys for Plaintiffs AstraZeneca
Pharmaceuticals LP, AstraZeneca UK
Limited, Kudos Pharmaceuticals Limited, The
University of Sheffield, and MSD
International Business GmbH*

SO ORDERED THIS 13th day of November 2023.


The Honorable Robert Kirsch, U.S.D.J.